

K110173

510(k) Summary
for the
E.M.S. Electro Medical Systems SA
EMS AIR-FLOW MASTER PIEZON

APR - 7 2011

1. SUBMITTER/510(k) HOLDER

E.M.S. Electro Medical Systems SA
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Date Prepared: January 17, 2011

2. DEVICE NAME

Proprietary Name: EMS AIR-FLOW MASTER PIEZON
Common/Usual Name: Ultrasonic Scaler/Air Polishing Unit
Classification Name: Ultrasonic Scaler (21 CFR 872.4850, Product Code ELC)*
**As will be discussed in Section 4, the EMS AIR-FLOW MASTER PIEZON combines the functions of an ultrasonic scaler and air-polishing unit. The predicate AIR-FLOW S2, which was cleared with dual ultrasonic scaler and air-polishing functions, was classified by FDA as an ultrasonic scaler.*

3. PREDICATE DEVICES

The proposed EMS AIR-FLOW MASTER PIEZON is substantially equivalent to the following legally marketed medical devices:

- E.M.S. Electro Medical Systems S.A., PIEZON MASTER 700 (K093000)
- E.M.S. Electro Medical Systems S.A., AIR-FLOW HANDY PERIO (K092289)
- E.M.S. Electro Medical Systems S.A., AIR-FLOW MASTER (K082791)
- E.M.S. Electro Medical Systems S.A., AIR-FLOW MASTER STANDARD (K073284)
- E.M.S. Electro Medical Systems S.A., AIR-FLOW S2 (K900709)
- E.M.S. Electro Medical Systems S.A., miniMaster LED (K093723)

The instruments used with the AIR-FLOW MASTER PIEZON were previously cleared by FDA:

- E.M.S. Electro Medical Systems S.A., miniMaster Ultrasonic Scaler (K050710)
- E.M.S. Electro Medical Systems S.A., EMS Kermit (K992504)
- E.M.S. Electro Medical Systems S.A., miniPiezon (K953026)
- E.M.S. Electro Medical Systems S.A., Piezon Master 400 (K896749)
- E.M.S. Electro Medical Systems S.A., PIEZON MASTER 600 (K022328)

4. DEVICE DESCRIPTION

The EMS AIR-FLOW MASTER PIEZON is a dental device that combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The proposed device consists of the base control unit, hoses and connectors for two handpieces, and a foot control containing a four-position switch. There are two mounts on the top of the base unit, one for an irrigation liquid container and the other for one of the two air-polishing chambers supplied with the device.

The AIR-FLOW MASTER PIEZON is supplied with the Piezon Handpiece LED for performing ultrasonic scaling functions. The proposed device is compatible with EMS instruments legally marketed for ultrasonic scaling procedures.

The AIR-FLOW MASTER PIEZON is also supplied with the AIR-FLOW Handpiece and PERIO-FLOW Handpiece for performing air-polishing procedures. The proposed device is compatible with the AIR-FLOW CLASSIC (sodium bicarbonate), AIR-FLOW SOFT (glycine), and AIR-FLOW PERIO (glycine) prophylaxis powders.

The AIR-FLOW MASTER PIEZON is supplied with accessories for attaching and removing instruments and nozzles from the handpieces and containers for storage and sterilization of the reusable components and accessories.

5. INTENDED USE

The AIR-FLOW MASTER PIEZON combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The AIR-FLOW MASTER PIEZON is intended for use in the following dental and periodontal applications:

- Removing supra and subgingival calculus deposits and stains from teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha
- Plugging for amalgam condensation
- Amalgam burnishing
- Preparing, cleaning and irrigating root canals

- Cavity preparation
- Cementing inlays and onlays
- Retrograde preparation of root canals

The AIR-FLOW MASTER PIEZON is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.

The AIR-FLOW MASTER PIEZON can be used for the following cleaning procedures:

- Plaque removal for placement of sealants
- Surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers
- Surface preparation prior to placing composite restorations
- Effective plaque and stain removal for orthodontic patients
- Cleaning prior to bonding ortho brackets
- Cleaning implant fixture prior to loading
- Stain removal for shade determination
- Plaque removal prior to fluoride treatment
- Plaque and stain removal prior to whitening procedure

The AIR-FLOW MASTER PIEZON is also intended for use as an air-polisher in patients suffering from periodontal disease. The AIR-FLOW MASTER PIEZON is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

6. PRINCIPLES OF OPERATION

The proposed AIR-FLOW MASTER PIEZON combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis to provide a complete prophylaxis solution. The working instrument for both the scaling and air-polishing functions is the handpiece, which is connected to the control unit via a power cord.

The AIR-FLOW MASTER PIEZON is configured with the scaling handpiece mounted in a holder on the left side of the control unit, and the air-polishing handpiece mounted on the right side of the control unit. The treatment method (Piezon ultrasonic scaling or Air-Flow air-polishing) is selected by removing the handpiece associated with the treatment method of interest from the holder.

As with other ultrasonic scalers, the ultrasonic generator housed in the AIR-FLOW MASTER PIEZON control unit generates piezo-electric vibrations. Instruments mounted in the Piezon Handpiece LED vibrate with a controlled oscillatory movement when activated.

Air-polishing procedures are carried out by placing the nozzle at the end of the handpiece at the treatment site and activating the handpiece. As with the ultrasonic scaling functions, the footswitch activates the flow of the air/water/powder mixture. When the footswitch is released, the air/water/powder flow stops immediately. The practitioner controls the air-polishing treatment using the touch panels on the control panel and the footswitch to regulate the air/powder flow rate and the flow rate of the water into the handpiece.

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The proposed EMS AIR-FLOW MASTER PIEZON is substantially equivalent to the previously cleared AIR-FLOW S2, which also combines ultrasonic scaling and air-polishing functions in a single chassis. The design and function of the ultrasonic scaling and air-polishing functional units of the proposed AIR-FLOW MASTER PIEZON are substantially equivalent to the PIEZON MASTER 700 ultrasonic scaler and the AIR-FLOW MASTER and AIR-FLOW MASTER STANDARD air-polishing units. Differences between the proposed AIR-FLOW MASTER PIEZON and the predicate PIEZON MASTER 700 ultrasonic scaler and AIR-FLOW MASTER and AIR-FLOW MASTER STANDARD air-polishing units are limited to those hardware and firmware modifications necessary to integrate these functionalities into a single chassis.

Testing demonstrated that the AIR-FLOW MASTER PIEZON fulfills the prospectively defined performance specifications. The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed AIR-FLOW MASTER PIEZON and the predicate AIR-FLOW S2, PIEZON MASTER 700, AIR-FLOW MASTER, and AIR-FLOW MASTER STANDARD lead to a conclusion of substantial equivalence between the proposed and predicate devices. A side-by-side comparison of the predicate devices and the proposed device is provided in Table 5-1 at the end of this section.

8. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Testing was performed to verify compliance of the AIR-FLOW MASTER PIEZON with the following standards:

- ANSI/AAMI ST79:2006, "Comprehensive guide to steam sterilization and sterility assurance in health care facilities"
- ISO 17664 (2004), "Sterilization of Medical Devices – Information to be provided by the Manufacturer for the Processing of Resterilizable Medical Devices"
- ANSI/AAMI/ISO 17665-1:2006 "Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices"
- IEC 60601-1:1988 +A1: 1991 + A2: 1995, "Medical electrical equipment, Part1: General requirements for safety"
- IEC 60601-1-2, "Medical electrical equipment. Part 1 General requirements for safety – Part 2 Collateral standard: Electromagnetic compatibility: Requirements and Tests" (2007).
- ISTA 2A (2008), "ISTA Preshipment Testing Procedures- Combination Tests for Packaged-Products 150 lb (68 kg) or Less"

The results of this testing confirm that the AIR-FLOW MASTER PIEZON is safe and effective for the intended use described in Section 5.

9. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted for this submission.

10. SUMMARY OF OTHER INFORMATION

No other information is available.

11. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information and supporting documentation provided in the premarket notification, the EMS AIR-FLOW MASTER PIEZON is substantially equivalent to the cited predicate devices. Testing demonstrates that the EMS AIR-FLOW MASTER PIEZON fulfills prospectively defined design and performance specifications.

Table 5-1. Comparison Table for Determination of Substantial Equivalence

Item for Comparison	EMS AIR-FLOW MASTER PIEZON Proposed	EMS PIEZON MASTER 700 K093000	EMS AIR-FLOW MASTER K082791	EMS AIR-FLOW MASTER STANDARD K073284	AIR-FLOW S2 K900709
Indications for Use	<p>Intended for use in dental and periodontal applications performed by an ultrasonic scaler.</p> <p>Intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface.</p> <p>Intended for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.</p>	<p>Intended for use in dental and periodontal applications performed by an ultrasonic scaler.</p>	<p>Intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface.</p> <p>Intended for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.</p>	<p>Intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface.</p>	<p>Intended for use in dental and periodontal applications performed by an ultrasonic scaler.</p> <p>Intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface.</p>
Treatment Site Function	Subgingival and supragingival Ultrasonic scaling and air-polishing	Subgingival and supragingival Ultrasonic scaling	Subgingival and supragingival Air-polishing	Supragingival Air-polishing	Supragingival Ultrasonic scaling and air-polishing
Mechanism of action	<ul style="list-style-type: none"> Ultrasonic energy Projection of water/air/powder mixture 	Ultrasonic energy	Projection of water/air/powder mixture	Projection of water/air/powder mixture	<ul style="list-style-type: none"> Ultrasonic energy Projection of water/air/powder mixture
Components	<ul style="list-style-type: none"> Control Unit Powder chambers Irrigation liquid bottle Foot pedal Piezon Handpiece LED AIR-FLOW Handpiece PERIO-FLOW Handpiece PERIO-FLOW Slim Nozzle* Instruments 	<ul style="list-style-type: none"> Control Unit Irrigation liquid bottle Foot pedal Piezon Handpiece LED Instruments 	<ul style="list-style-type: none"> Control Unit Powder chambers Foot pedal AIR-FLOW Handpiece PERIO-FLOW Handpiece PERIO-FLOW Nozzle 	<ul style="list-style-type: none"> Control Unit Powder chamber Foot pedal Piezon Handpiece AIR-FLOW Handpiece Instruments 	<ul style="list-style-type: none"> Control Unit Powder chamber Foot pedal Piezon Handpiece AIR-FLOW Handpiece Instruments
Prophylaxis Powders for Use with System	<ul style="list-style-type: none"> PERIO (Glycine) SOFT (Glycine) CLASSIC (Sodium Bicarbonate) 	Not applicable	<ul style="list-style-type: none"> PERIO (Glycine) SOFT (Glycine) CLASSIC (Sodium Bicarbonate) 	<ul style="list-style-type: none"> AIR-FLOW (Sodium bicarbonate) 	<ul style="list-style-type: none"> AIR-FLOW (Sodium bicarbonate)

*Cleared for marketing in K092289 (AIR-FLOW Handy Perio)



Food and Drug Administration
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C/O Cynthia J. M. Nolte, PhD, RAC
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APR - 7 2011

Re: K110173
Trade/Device Name: EMS AIR-FLOW MASTER PIEZON
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC, EFB, and EJR
Dated: January 17, 2011
Received: January 20, 2011

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

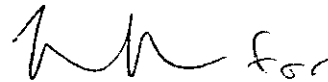
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: EMS AIR-FLOW MASTER PIEZON

Indications for Use:

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- cleaning implant fixture prior to loading
- stain removal for shade determination
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- plaque and stain removal prior to whitening procedure

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110173